



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/643,294 | 08/22/2000 | Kartikeya P. Pathak | 16693-2 | 8366 |

7590 06/14/2005

Clifford W Browning
Woodard Emhardt Naughton Moriarty McNett
Bank One Center Tower
111 Monument Circle Suite 3700
Indianapolis, IN 46204

| |
|----------|
| EXAMINER |
|----------|

ROBERT, EDUARDO C

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3732

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/643,294

Applicant(s)

PATHAK, KARTIKEYA P.

Examiner

Eduardo C. Robert

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 12, 2004 has been entered.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in India on May 3, 1998. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

Specification

The substitute specification filed April 12, 2004 **has not been entered** because it does not conform to 37 CFR 1.125(b) and (c) because: A statement that the substitute specification includes no new matter is not present. Furthermore, a specification with markings to show all the changes relative to the **immediate** prior version is not present.

The specification, for examination purposes, is the one filed on April 8, 2003. Thus, rejections and objections made on the last office action, mailed on December 4, 2003, are applicable and they are set forth below.

Art Unit: 3732

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The amendment filed on April 8, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

In page 2, line 10, "plant biology" is new matter.

In page 9, line 13, through page 10, line 4, is new matter.

In page 10, line 7-8, "with self-cutting capabilityexpedient" is new matter. Also, in lines 10-13, "has no chance of catching either smoothly" is new matter. In lines 14-17, "which is capable of ... bone surface" is new matter. In lines 18-20, "to be fixed in a desired position ... rod" is new matter. In lines 21-22, "The head 4 ... turning" is new matter.

In page 11, lines 2-8, "It also serves for ... countersink" is new matter. In line 10, "or faceted" is new matter. In lines 13-21, "Since a lag screw a tap" is new matter.

In page 12, line 2, through page 13, line 21, "A higher load will the rod" is new matter.

In page 14, line 6, "The compression ... off" is new matter. Also, in lines 6-8, "Sliding of screw ... the part" is new matter.

In page 14, line 20, through page 15, line 7, "In the event ... to unite" is new matter.

In page 16, lines 1-2, "with spherical heads ... contact" is new matter. In line 6 through page 17, line 11, "FIG 8 is one type ... phenomenon" is new matter.

Also, Figures 3, 7, 8-12 are considered new matter.

It is noted that the new matter is not supported by the disclosure as originally filed and it is so much that an example of a new matter will be discussed, however, applicant is required to cancel the new matter or explain from where in the original disclosure it is coming.. An example follows, the disclosure or drawing or claims as originally filed do not disclose new Figures 8-12 or the description of the figures.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 28, lines 1 and 2, “further comprising a mobile head capable of refixation at different levels between the thread and the second end” is new matter. As originally filed the implant was not described as including two heads in the same implant, e.g. one fixed (see parent claim 26) and one mobile (see dependent claim 28). Thus, this is clearly new matter. *It is noted that as disclosed the head of the implant could be mobile and claim 28 would be considered as*

claiming that the head can be mobile. Furthermore, if applicant desire to claim that the head can be mobile, it is noted that claim 26 must be amended to prevent a 35 USC 112, second paragraph, e.g. "an intercalated fixed spherical head" should be changed to -- an intercalated spherical head", since a head that is fixed is not mobile.

Claim 29 has the same problem of claim 28 and it would be treated for examination purposes in the same manner as claim 28.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 25-29 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 25, lines 3-4, applicant positively recites part of a human, i.e. "a second end outside the skin". In claim 26, applicant positively recites part of a human, i.e. "a second end outside the ski". Thus claims 25-29 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

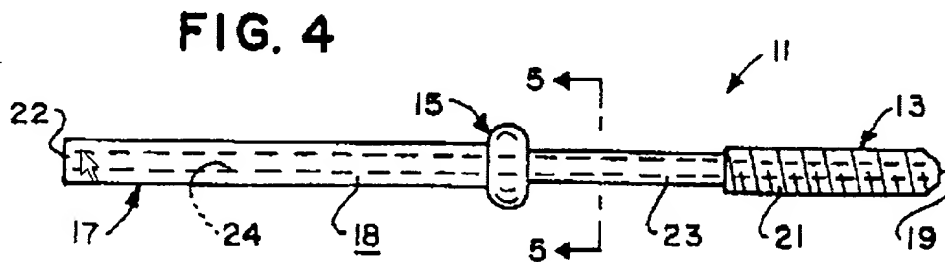
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al.

(U.S. Patent No. 5,690,633 cited on PTO-892 mailed on 11/07/01).

Taylor et al. disclose an implant 11 (see Figure 4 below). The implant 11 includes a first end with a thread 21 and a second end 22 which would constitute a grip. The implant 11 further includes an intercalated fixed spherical head 15. It is noted that the head 15 is considered “spherical” since it includes a segment of an sphere. The *Merriam-Webster Online Dictionary* defines “spherical” as “having the form of a sphere or of one of its segments”. Thus, head 15 is considered “spherical”.



The implant is partially threaded from the first end, stopping short of the head 15 (see Figure 4 above). The implant also includes a smooth shaft 23 between the thread 21 and the head 15 and an extended rod 18 from the head 15 to the second end 22. The implant is canalized, e.g. at 24, from the first end to second end throughout. The head 15 can be mobile (see col. 7, lines 1-6). Taylor et al. disclose and show that the shape of the head can change, e.g. having a conical

shape (see Figures 6). Also, Taylor disclose that the implant can have the threads expanding from the first end to the head, as shown in Figure 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Patent No. 5,690,633 cited on PTO-892 mailed on 11/07/01).

Taylor et al. disclose the claimed invention except for the head having a conical shape with a blunt serrated margin. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant of Taylor et al. with the head having a conical shape with a blunt serrated margin, since it is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an element that would abut bone. In re Dailey and Eilers, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments filed April 12, 2004 have been fully considered but they are not persuasive.

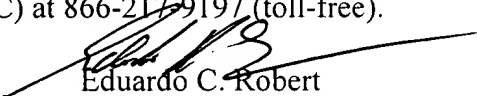
In response to applicant's arguments and statements, it is noted that the substitute specification filed on April 12, 2004 was not entered for the reasons set forth above (see "Specification" section). Thus, the new matter problems have not been solved.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.